UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,425	02/19/2002	Harold G. Brown	2059-0103P	1812

2292 7590 02/10/2006

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
PRATS, FRANCISCO CHANDLER	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,425	BROWN ET AL.	
	Examiner	Art Unit	
	Francisco C. Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *3,8,9,13,24-27,30-35,52,60,63-65,67,96-111 and 116* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 6, 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-94, 112-115 and 117-124* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11-14-2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 2,3,6-9,11-14,19,22-27,30-37,41,42,46-54,59,60,63-67,69,70,72-94 and 96-124.

DETAILED ACTION

The amendment filed November 14, 2005, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 2, 3, 6-9, 11-14, 19, 22-27, 30-37, 41, 42, 46-54, 59, 60, 63-67, 69, 70, 72-94 and 96-124 are pending.

Election/Restrictions

Applicant's election with traverse, in the paper filed December 15, 2003, of the group II invention, directed to glycosaminoglycan-containing compositions which do not contain essential oils, is acknowledged. Applicant's election of hyaluronic acid as the therapeutic compound is also acknowledged.

Claims 3, 8, 9, 13, 24-27, 30-35, 52, 60, 63-65, 67, 96-111 and 116 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. As noted above, applicant timely traversed the restriction (election) requirement in the paper filed December 15, 2003.

As amended 2, 6, 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-94, 112-115 and 117-124 read on compositions comprising a glycosaminoglycan in the absence of an essential oil, the invention elected by applicant, and encompass hyaluronic acid, the species of glycosaminoglycan elected by applicant. Amended claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-94, 112-115, 117 and 118-124 are therefore examined on the merits, to the extent they read on compositions comprising hyaluronic acid.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 122 and 123 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. Specifically, the recitation requiring 0.0001 mg to 100 mg of the polysaccharide to be in the composition is considered new matter. More specifically, the only recitation of this range in the as-filed specification appears on line 29 of page 26 of the specification. However, that sentence states that the ***dosage*** should be 0.0001 mg and 100 mg, not that the composition possesses that range of active ingredient amounts. Moreover, taken in context, the sentence on page 26 appears to be stating a dosage for a mixture of hyaluronic acid and chondroitin sulfate, whereas the claims are not so limited.

All of applicant's argument regarding this ground of rejection has been fully considered, but is not persuasive of error. While applicant urges misinterpretation of the specification in assessing support for this limitation, applicant does not point out why the above interpretation is incorrect.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 93 and 121 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 93's recitation of the term "low purity hyaluronic acid" remains indefinite because the term "low" is entirely subjective, and therefore it is unclear what the purity must be.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 23, 42, 50, 51, 59, 66, 70, 72-76, 78, 80, 81, 91-95, 112, 117-121 and 124 are rejected under 35 U.S.C. 102(b) as being anticipated by Balazs (U.S. Pat. 4,303,676).

Balazs discloses a product comprising a low molecular weight hyaluronate fraction having a molecular weight of 10,000 to 200,000, a high molecular weight hyaluronate fraction having a molecular weight from 1 to 4.5 million, 50 to 400% protein (based on the weight of the hyaluronate), and water. See column

1, line 64 through column 2, line 6. In a preferred embodiment the product, designated as "HPE", is a visco-elastic liquid containing about 1% sodium hyaluronate, 0.5 to 1.5% protein and 97.5 to 98.5% water. See column 4, lines 59-68.

The limitation in the claims requiring an inflammatory response upon injection into owl monkey eyes is considered to be met, because the prior art composition contains all of the claimed ingredients, and in the claimed amounts, including the claimed amounts of impurities. In this regard applicant's attention is directed to page 4 of the instant specification wherein it is stated that cosmetic grade products will not pass the owl monkey eye test. Because the product of Balazs contains the claimed amount of impurities, and because Balazs' product is a cosmetic grade product, the product of Balazs will likewise not pass the owl monkey eye test, as required in the claims as amended.

The limitation requiring no reaction on the skin is clearly met by Balazs. See column 4, lines 33-43, wherein HPE produces no reactivity with skin. The requirement in claim 72 of "up to about 5% impurities" is considered to be met by Balazs because of the 0.5 to 1.5% protein present in the HPE product. Because the claimed ingredients are present in the claimed concentrations, a holding of anticipation is required.

It is noted that the composition is not designated as being for oral administration, or that it has any nutritional value. However, as discussed above, the HPE composition disclosed by Balazs is in liquid form, and therefore clearly can be administered orally, and therefore can be considered a food or drink or nutrient. Moreover, the product clearly can be absorbed mucosally. Note that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Because Balasz's compositions can be administered orally, and because they are in the form of food and drink, as those terms are properly construed most broadly, a holding of anticipation is clearly required.

All of applicant's argument regarding the holding of anticipation over Balazs has been fully considered, and reconsidered, but is not persuasive of error. Applicant initially urges that Balazs does not teach a composition having

a pharmacological composition having an amount of active ingredient that is medically effective as recited in the rejected claims. However, Balazs clearly discloses a composition having the claimed active ingredient. The term "pharmacologically effective amount" reads on virtually any amount of the ingredient, since any amount will have some pharmacological effect. Moreover, as discussed above, the preferred embodiment of Balazs, HPE, clearly contains 1% hyaluronic acid, and examples are disclosed wherein 200 milligrams of HPE are present (column 5, line 40). The the exemplified amount of HPE contains 2 milligrams of hyaluronic acid. In view of the fact that applicant's own claims 123 and 124 recite amounts as low as 0.0001 mg of hyaluronic as being pharmacologically effective, it is clear that the various compositions in Balazs meet the limitation requiring the presence of the active ingredient in a "pharmacologically effective amount."

With respect to whether Balazs '676 discloses a food or drink as required in the claims under examination, it is respectfully pointed out that the preferred embodiment, HPE, is a "sterile liquid." Column 4, line 61. One can drink a sterile liquid. Thus, while the intended route of administration of the claimed composition is different than the intended route of

administration of Balazs' compositions, the claims under examination encompass Balazs' compositions.

Lastly, it is specifically noted that the cited reference does not explicitly disclose whether the disclosed hyaluronic acid-containing products cause an inflammatory response when injected into owl monkey eyes. However, the fact remains that the prior art products contain all of the claimed ingredients, and in the claimed amounts, including the claimed amounts of impurities, in a product grade admitted by applicant (specification, page 4) to generate the required inflammatory response.

It is therefore properly assumed, that the prior art products inherently possess the same properties as the claimed products. Significantly, applicant provides no factual evidence whatsoever to refute the holdings of anticipation with respect to the limitation requiring an adverse reaction in the owl monkey eye test. Note specifically that on the current record virtually the only way of overcoming such a clear holding of anticipation is factual proof that the rejection is in error. *See* MPEP § 2112, disclosing that once a proper holding of anticipation is made, the burden shifts to applicant to demonstrate an unobvious difference between the claims and the prior art. *See also, In re Best*, 562 F.2d 1252, 1255, 195 USPQ

430, 433 (CCPA 1977) ("the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product"). Because applicant has not demonstrated any difference between the claimed products and the prior art products, the rejection of record clearly must be maintained.

Claims 19, 22, 23, 42, 50, 51, 59, 66, 70, 72-76, 78, 80, 81, 91-95, 112, 117-121 ad 124 are rejected under 35 U.S.C. 102(b) as being anticipated by Turley et al (WO 97/25051).

Turley discloses orally administrable hyaluronic acid compositions. See abstract. The preferred products are disclosed as being in liquid drink form. See, e.g., page 12, lines 20-22. The molecular weight of the hyaluronic acid can range from 30,000 to 2,000,000 Daltons, thereby encompassing all of the molecular weight fractions recited in the rejected claims. See claim 1, on page 26.

In view of the protein present in the composition (see pages 7-11, disclosing the makeup of the compositions) the requirement of an inflammatory response upon injection into owl monkey eyes is considered to be met, particularly since the

prior art composition contains all of the claimed ingredients, and in the claimed amounts, including the claimed amounts of impurities. In this regard applicant's attention is again directed to page 4 of the instant specification wherein it is stated that cosmetic grade products will not pass the owl monkey eye test. Because acceptable products according to Turley can be of "topical grade" (see pages 8 and 9), acceptable products according to Turley will likewise not pass the owl monkey eye test, as required in the claims as amended.

All of applicant's argument regarding the Turley reference has been fully considered but is not persuasive of error. While applicant again points to a statement in Turley discussing the undesirable properties of hyaluronic acid of over 1,000,000 Daltons (page 12), this statement must be taken in the full context of the reference's disclosure (claim 1 on page 26; see also claim 12 on page 27), which unequivocally states that the high molecular weight can be used. Even conceding that the high molecular weight hyaluronic acid is a non-preferred embodiment, it is well established that non-preferred embodiments in the prior art are properly considered to anticipate and/or render obvious claims encompassing the non-preferred subject matter.

Also, while applicant urges that Turley does not use hyaluronic acid of the claimed purity, applicant does not point

to any facts supporting this statement. In fact, Turley discloses a "topical grade" HA which contains significant protein but can be administered orally upon sterilization (see pages 8 and 9). Turley's preparation thus appears identical to the "low purity" product described by applicant (e.g., specification at pages 14-15). Lastly, as to the fact that applicant's products do not require sterilization, it is respectfully pointed out that applicant's product claims do not exclude sterilized products. Thus, despite the sterilization of the materials in Turley, the claims under examination encompass the products disclosed in Turley.

It is again specifically noted that the cited reference does not explicitly disclose whether the disclosed hyaluronic acid-containing products cause an inflammatory response when injected into owl monkey eyes. Again, however, the fact remains that the prior art products contain all of the claimed ingredients, and in the claimed amounts, including the claimed amounts of impurities, in a product grade admitted by applicant (specification, page 4) to generate the required inflammatory response.

It is therefore properly assumed, that the prior art products inherently possess the same properties as the claimed products. Significantly, applicant provides no factual evidence

whatsoever to refute the holdings of anticipation with respect to the limitation requiring an adverse reaction in the owl monkey eye test. Note specifically that on the current record virtually the only way of overcoming such a clear holding of anticipation is factual proof that the rejection is in error. *See* MPEP § 2112, disclosing that once a proper holding of anticipation is made, the burden shifts to applicant to demonstrate an unobvious difference between the claims and the prior art. *See also, In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) ("the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product"). Because applicant has not demonstrated any difference between the claimed products and the prior art products, the rejection of record clearly must be maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the

> art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-94, 112-115 and 117-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balazs (U.S. Pat. 4,303,676).

As discussed above, because Balazs explicitly discloses orally administrable compositions of hyaluronic acid in liquid form, Balazs is considered to anticipate numerous embodiments recited in applicant's claims. Balazs differs from certain of the claimed embodiments in that Balazs does not disclose that the compositions comprise 0.0001 mg to 100 mg of HA. However,

Balazs clearly discloses that the formulations therein may contain from 0.05 to 5% of the HPE liquid composition. See column 5, lines 32-33. As discussed above, the HPE composition in turn contains about 1% sodium hyaluronate. Thus, in Balazs' preferred embodiment of a liquid of about 100 ml (spanning columns 5 and 6), the composition could contain up to 5 grams of HPE, which in turn would contain 0.05 grams (50 milligrams) of hyaluronic acid. Thus, while not explicitly disclosed, the claimed amounts of HA are within those suggested by Balazs as being suitable for use therein. A holding of obviousness is therefore required.

Balazs also differs from certain embodiments recited in the claims under examination by failing to explicitly disclose the use of all of the claimed oral administration forms, including tablets, capsules and food supplements, including animal treats, as the physical form of the orally administrable hyaluronic acid compositions disclosed therein. However, in view of Balazs' clear disclosure of a liquid form suitable for oral administration, the artisan of ordinary skill would have considered all of the claimed liquid oral vehicles obvious in view of Balazs. A holding of obviousness is therefore required.

All of applicant's argument regarding this ground of rejection has been fully considered, but is not persuasive of

error. With respect to the assertion that the rejection of record fails to give patentable weight to the limitation requiring the product to create an inflammatory response in the owl monkey eye test, it is respectfully submitted that this limitation has been accorded patentable weight. As discussed above with respect to the rejection of claims under § 102 by Balazs, the limitation in the claims requiring an inflammatory response upon injection into owl monkey eyes is considered to be met, because the prior art composition contains all of the claimed ingredients, and in the claimed amounts, including the claimed amounts of impurities, and because page 4 of the instant specification states that cosmetic grade products will not pass the owl monkey eye test. Because the product of Balazs contains the claimed amount of impurities, and because Balazs' product is a cosmetic grade product, the product of Balazs will likewise not pass the owl monkey eye test, as required in the claims as amended.

With respect to the assertion that Balazs does not suggest the claimed amounts of the active ingredient, hyaluronic acid, it is respectfully submitted that, as discussed above, Balazs clearly discloses that the formulations therein may contain from 0.05 to 5% of the HPE liquid composition (column 5, lines 32-33), and that the HPE composition in turn contains about 1%

sodium hyaluronate. Thus, in Balazs' preferred embodiment of a liquid of about 100 ml (spanning columns 5 and 6), the composition could contain up to 5 grams of HPE, which in turn would contain 0.05 grams (50 milligrams) of hyaluronic acid. Thus, while not explicitly disclosed, the claimed amounts of HA are within those suggested by Balazs as being suitable for use therein.

As to the assertion that Balazs's compositions do not contain the claimed active ingredient, it is respectfully pointed out that Balazs discloses a product comprising a low molecular weight hyaluronate fraction having a molecular weight of 10,000 to 200,000, a high molecular weight hyaluronate fraction having a molecular weight from 1 to 4.5 million, 50 to 400% protein (based on the weight of the hyaluronate), and water (column 1, line 64 through column 2, line 6), and in a preferred embodiment the product, designated as "HPE", is a visco-elastic liquid containing about 1% sodium hyaluronate, 0.5 to 1.5% protein and 97.5 to 98.5% water (column 4, lines 59-68). In sum, Balazs clearly provides motivation for preparing less pure, e.g. cosmetic grade, hyaluronic acid preparations with the claimed molecular weights, in physical forms which are encompassed by the claims under examination.

Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-94, 112-115 and 117-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turley et al (WO 97/25051).

As discussed above, because Turley explicitly discloses orally administrable compositions of hyaluronic acid in drink form, Turley is considered to anticipate numerous embodiments recited in applicant's claims. Turley differs from certain of the claimed embodiments in that Turley does not disclose that the compositions comprise 0.0001 mg to 100 mg of HA. However, Turley clearly discloses that the dosage for the therapeutic methods disclosed therein may contain from 3 to 100 mg/kg body weight of the patient. See claim 1, page 26. Thus, the selection of a specific amount of active ingredient in a dosage form suitable for Turley's disclosure would have been an obvious matter of judicious selection on the part of the artisan of ordinary skill, said artisan recognizing that pill/tablet size, etc. were result effective parameters routinely optimized in the pharmaceutical arts at the time of applicant's invention. For example, at Turley's 3 mg/kg dosage for a 60 kg adult, one could administer two 90 mg tablets. Thus, one of ordinary skill in the art would have been motivated to have created any dosage

forms, such as the proposed 90 mg tablets, suitable for administering the dosage amounts indicated by Turley.

Turley also differs from certain embodiments recited in the claims under examination by failing to explicitly disclose the use of all of the claimed oral administration forms, including tablets, capsules and food supplements, including animal treats, as the physical form of the orally administrable hyaluronic acid compositions disclosed therein. However, in view of Turley's clear disclosure that oral administration was a suitable method of giving hyaluronic acid to patients, the artisan of ordinary skill would have considered all of the claimed oral vehicles obvious forms of administering the hyaluronic acid compositions of Turley. A holding of obviousness is therefore required.

Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-94, 112-115 and 117-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turley et al (WO 97/25051) in view of Gallina (WO 92/22585).

As discussed above, because Turley explicitly discloses orally administrable compositions of hyaluronic acid in drink form, Turley is considered to anticipate numerous embodiments recited in applicant's claims. Turley differs from certain of

the claimed embodiments in that Turley does not disclose the preparation of a suppository, per se.

However, Gallina discloses rectally administrable hyaluronic acid compositions. See abstract. The products are disclosed as being suitably "incorporated into numerous types of gels, creams, ointments, lotions, pastes, salves, liquids, and/or suppository vehicles." See page 6, lines 17-20. The hyaluronic acid useful in the compositions may have a molecular weight from 50,000 up to 8,000,000 Daltons. See page 1, lines 23-28. Thus, the artisan of ordinary skill practicing Turley's invention clearly would have been motivated to have formulated the HA preparations in the form of suppositories and rectally administrable forms, based on Turley's disclosure of the suitability of administering hyaluronic acid by that method. Alternatively, the artisan of ordinary skill practicing Gallina's method would have been motivated to have used the hyaluronic acid preparations disclosed by Turley in suppository or rectally administrable forms, based on the fact that Turley's HA preparations were known to possess the critical agent disclosed by Gallina, and were disclosed by Turley as having a therapeutic effect.

All of applicant's argument regarding the obviousness rejections based on Turley have been considered and

reconsidered, but are not persuasive of error. With respect to the argument that Turley states on page 12, lines 8-14, that hyaluronic acid "will not be orally effective[,]" it is respectfully pointed out that the cited passage states only that the hyaluronic acid "does not interact very well with HA receptors" and that such molecules should be "avoided." However, that same passage does allow that higher molecular weight species can be used if diluted.

Also, applicant's attention is directed to page 25 of Turley, wherein the molecular weight according to the "Dextran Standard" is disclosed as being 3.3 times the molecular weight according to the "Protein Standard"; thus the topical grade product at page 9 of Turley has a molecular weight well within the claimed range, when using he Dextran Standrard.

Moreover, just as it is improper to ignore portions of a reference which teach away from the claimed subject matter, it is improper to ignore portions of a reference which suggests the practice of the claimed invention. Thus, because Turley clearly discloses (e.g. specification at pages 4 and 5) and claims (claims 1 and 12) orally effective compositions comprising hyaluronic acid having a molecular weight as claimed, Turley provides motivation for practicing the claimed subject matter.

With respect to the assertion that Turley does not disclose a hyaluronic acid having the claimed purity, it is again noted that Turley discloses "topical grade" hyaluronic acid preparations having significant impurities, and that these topical preparations would appear to be the same grade of product as the "cosmetic grade" preparations disclosed at page 4 of the specification as meeting the claimed limitation regarding the owl monkey eye test. In sum, Turley clearly provides motivation for preparing less pure, e.g. topical grade, hyaluronic acid preparations with the claimed molecular weights, in physical forms which are encompassed by the claims under examination. The rejections of record must therefore be maintained.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened

statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Francisco C. Prats
Primary Examiner
Art Unit 1651

FCP